

PUBLIC HEALTH COUNCIL

Meeting of the Public Health Council held Tuesday, February 22, 2005, 10:00 a.m., at the Massachusetts Department of Public Health, 250 Washington Street, Boston, Massachusetts. Public Health Council Members present were: Christine C. Ferguson, Chair, Commissioner, Department of Public Health (arrived late at 10:25 a.m.), Ms. Suzanne Thomson, Deputy Commissioner, Department of Public Health, Acting Chair, Ms. Maureen Pompeo, Mr. Albert Sherman, Ms. Janet Slemenda, Dr. Thomas Sterne, Mr. Gaylord Thayer, Jr., and Dr. Martin Williams. Absent Members were Ms. Phyllis Cudmore and Mr. Manthala George, Jr.. Also in attendance was Attorney Donna Levin, General Counsel.

Acting Chair, Ms. Suzanne Thomson, announced that notices of the meeting had been filed with the Secretary of the Commonwealth and the Executive Office of Administration and Finance.

The following members of the staff appeared before the Council to discuss and advise on matters pertaining to their particular interests: Dr. Paul Dreyer, Associate Commissioner, Dr. Grant Carrow, Deputy Director, Ms. Roberta Bernstein, Program Coordinator, Center for Quality Assurance and Control; Ms. Karen Edlund, Director of Family Planning; Mr. Howard Wensley, Acting as Commissioner's Designee for the Department of Public Health; Ms. Joan Gorga, Acting Director, and Mr. Jere Page, Senior Analyst, Determination of Need Program.

RECORDS:

After consideration, upon motion made and duly seconded, it was voted (unanimously) to approve the Records of the Public Health Council Meeting of January 18, 2005.

PERSONNEL ACTIONS:

In a letter dated February 7, 2005, Val W. Slayton, MD, MPP, Chief Medical Officer, Tewksbury Hospital, Tewksbury, recommended approval of the following physician to the medical staff of Tewksbury Hospital. After consideration of the appointee's qualifications, upon motion made and duly seconded, it was voted (unanimously) that, in accordance with the recommendation of the Chief Medical Officer of Tewksbury Hospital, under the authority of the Massachusetts General Laws, chapter 17, section 6, the following reappointment to the medical staff of Tewksbury Hospital be approved for the period of February 1, 2005 to February, 2007.

<u>REAPPOINTMENTS:</u>	<u>MASS. LICENSE NO.:</u>	<u>STATUS/SPECIALTY:</u>
Walter Levitsky, MD	26773	Active: Internal Medicine Consultant: Neurology

In a letter dated January 28, 2005, Blake M. Molleur, Executive Director, Western Massachusetts Hospital, Westfield, recommended approval of the following physicians/dentists to the consulting medical staff of Western Massachusetts Hospital. After consideration of the appointees' qualifications, upon motion made and duly seconded, it was voted (unanimously) that, in accordance with the recommendation of the Executive Director of Western Massachusetts

Hospital, under the authority of the Massachusetts General Laws, chapter 17, section 6, the following reappointments to the consulting medical staff of Western Massachusetts Hospital be approved:

<u>REAPPOINTMENTS:</u>	<u>MASS. LICENSE NO.:</u>	<u>STATUS/SPECIALTY:</u>
William Dean III, MD	75273	Neurology
Jonathan Slater, MD	81014	Nephrology
Denise Barresi, DMD	20699	Dentistry
Juliette Ochola, DDS	19020	Dentistry

In a letter dated February 14, 2005, Paul Romary, Executive Director, Lemuel Shattuck Hospital, Jamaica Plain, recommended approval of the initial appointments and reappointments to the various medical and allied health staffs of Lemuel Shattuck Hospital. After consideration of the appointees' qualifications, upon motion made and duly seconded, it was voted (unanimously) that, in accordance with the recommendation of the Executive Director of Lemuel Shattuck Hospital, under the authority of the Massachusetts General Laws, chapter 17, section 6, the following appointments and reappointments to the various medical and allied health staffs of Lemuel Shattuck Hospital be approved:

<u>APPOINTMENTS:</u>	<u>MASS. LICENSE NO.:</u>	<u>STATUS/SPECIALTY:</u>
Ritsh Dhar, MD	223200	Consultant/Internal Medicine
Steven Hatch, MD	223160	Consultant/Internal Medicine
Cathal O'Sullivan, MD	222391	Consultant/Pathology
<u>APPOINTMENTS:</u>	<u>MASS. LICENSE NO.:</u>	<u>STATUS/SPECIALTY:</u>
Barbara McGovern, MD	74283	Active/Infectious Disease
Benjamin Smith, MD	76962	Active/Gastroenterology
Marie Turner, MD	45947	Active/Pulmonary Medicine
David Cherniak, MD	159570	Consultant/Radiology
Joseph Polak, MD	46031	Active/Radiology
Carla Ross, MD	79076	Consultant/Radiology
Shoba Sequeira, MD	40122	Consultant/Radiology
Muhammed Absar, MD	152608	Active/Psychiatry
Marianne Hughes, DMD	18484	Consultant/Dentistry
Bonnie Zimble, DMD	17907	Consultant/Dentistry
Steven Schwaizberg, MD	55759	Consultant/Surgery
Elizabeth Kennedy	146061	Nurse Practitioner

STAFF PRESENTATION: “The Resident Empowerment Program in Nursing Homes”, by Paul Dreyer, PhD, Associate Commissioner and Ms. Roberta Bernstein, Center for Quality Assurance and Control

Dr. Dreyer made introductory remarks. Ms. Roberta Bernstein made a slide presentation to the Council. Some excerpts from the presentation follow:

“... We have been doing this program for five years, and other states have similar programs, but Massachusetts has been consistent in doing it over five years, and we have seen a rise in both the number of proposals received, as well as a diversity of ideas. Scattered throughout my presentation, I have pictures of various programs. This was Quinabog on the Common, and they have a hand chime choir, and they also have student volunteers. We have actually awarded Quinabog two proposal grants, the first to initiate the program and the second because there is so much resident interest, they wanted to purchase more chimes.”

“This program falls under Mass. General Law for the use of Civil Money Penalties, and Civil Money Penalties are charged to some nursing homes that are out of compliance with regulations. Mass. General Law states that DPH will use the funds to protect the welfare of their nursing home residents. We, in turn, request proposals that fulfill the protection provision by reaching residents’ lives with events, activities, or changes to the environment. In the RFR, we say that it could be as simple as bringing a smile to a residents’ face.”

“Our overarching goal is to improve the quality of life of residents, and we do this through resident participation and planning and implementation, and this gives them new found control over their lives, not always experienced in this institutional living. We encourage developing partnerships as another key element. We encourage facilities to work with groups in surrounding communities, to enliven the homes, and expand volunteer pools. Volunteers have also helped to reduce the overall cost of the program. Family and friends contribute immeasurably to resident happiness. Their involvement in activities bring them normalcy to daily life. And finally, we targeted funds to programs that supplement reimbursement that probably would not otherwise be available to residents.”

“A program at South Cove Manor in Chinatown. They have developed a very extensive program on Chinese art. The first phase was on practicing calligraphy. I spoke with the Activities Director last week and she mentioned that this year residents have been practicing Chinese art.”

“We have developed a fairly straightforward process. Each year, in the fall, we post an RFR and begin processing returns in early winter. Our criteria parallel resident empowerment goals. We assess the program’s ability to bring meaning to the lives of residents, the kind of partnerships being formed, how imaginative a program is, and the amount of outreach to volunteers, community and family. Another consideration is the facility’s ability to continue the program after the first year of funding. From time to time, we take into account intangibles that create a gut feel that we ought to fund the program. One such program was sending severely disabled children and their parents on a summer camping trip. To complete the process, the Committee ranks the proposals and makes their selections. The Committee members are from the Mass. Aging, Mass. Extended Care Federation, and the Ombudsman from the Executive Office of Elder Care.”

“We have grown from five proposals in 2001 to 56 in 2004 and we had 41 this year. The spike in 2004 was probably because facilities became aware that the maximum grant had risen to thirty thousand. We received 13 computer projects, and these can be Internet access of all kinds; looking at travel pictures, creating on-site the notion of a virtual life for residents; emails with family and friends, and one facility proposed a pen pal program with a local school. There are programs designed for the disabled. There were nine gardens, some of which are just very straightforward. One had a Portuguese theme because of a large Portuguese population, and another was a memorial with remembrances of past residents along a path. There were eight alternative or complementary therapy programs, and these are massage or aroma therapy. Seven music: many of these involved singing and playing instruments. Very often there is a concert to which everyone is invited after. The latter two tend to be expensive programs, more toward thirty thousand because of the cost of trained therapists. We had five facility redesign or remodeling, and this is an alteration of any current space, not required by regulations. There was one where they built a spa with some beauty parlor arrangement, the ability to do manicure and hand massage, and they brought family members in to learn how to do the family massage so that they could then do it with their loved ones. Another created a corner for a juke box and an ice cream stand, and the whole thing turned out to be rather creative.”

“There were four craft projects. Most of the craft projects have involved students from local schools, and with whatever it is they wind-up displaying it in the community, in the facility. Sometimes, they have sold some of the artwork, likewise with some of the garden projects, where they have produced vegetables. Volunteers have gone into the community and sold the produce. From both, the profits revert to the facility. There were two cultural exchange projects, which draw heavily on the “Eden concept”, which is creating a more homelike atmosphere, teamwork, and involving residents in the decision making.” Other projects noted were: conversion of a sparse dining room to an Italian Style Café; a fish tank for Alzheimer patients’ dining room; a bandstand, an MS patient taking photographs with an assistive device on his wheelchair.

In closing, Ms. Bernstein said, “In the future, we anticipate continuing the program year after year and we may request different themes as time goes on but we will maintain our overarching goal of improving quality of life of our state’s residents...”

Discussion followed by the Council. Council Member Slemenda asked for clarification on the funding of the program. Dr. Dreyer responded, “The amount comes in through Civil Monetary Penalties and that amount varies from year to year, depending on how much we collect from facilities for non-compliance. We try to set the amount of money each year so that we are never in danger. We haven’t yet spent more in a year than we have collected. Hopefully, the funding will be either self-perpetuating or else the facilities will improve with respect to compliance sufficiently so that the funds for the program might no longer be necessary.” Council Member Thayer, Jr. asked about the maintenance money for the projects. Ms. Bernstein replied, “Several places. A lot of them are able to, once the investment is made, maintain them out of their facility budgets, and with their own maintenance people. There also have been fund raisers. For more elaborate programs, they have sought out foundation grants.”

NO VOTE/INFORMATION ONLY

Note: At the close of the staff presentation above, Chair Ferguson arrived at the meeting at approximately 10:25 a.m.

PROPOSED REGULATION: INFORMATIONAL BRIEFING ON AMENDMENTS TO 105 CMR 700.000: IMPLEMENTATION OF M.G.L.C.94C:

Dr. Grant Carrow, Deputy Director, Center for Quality Assurance and Control, accompanied by Karen Edlund, Director of Family Planning, Center for Family and Community Health, presented the proposed amendments to 105 CMR 700.000 to the Council. Dr. Carrow noted the following: The Drug Control Program proposes to amend regulations at 105 CMR 700.000 to establish standards for the possession and dispensing of contraceptive medications by family planning clinics and agencies. The regulations would require registration of family planning agencies that dispense contraceptive medications and would establish standards that would include, but not be limited to:

1. authorizing appropriately trained and supervised staff to supply medications;
2. training and monitoring authorized staff;
3. properly packaging and labeling medications;
4. reporting medication errors and adverse events; and
5. recordkeeping.

Dr. Carrow provided an overview, “These amendments are expected to increase access to contraceptives and improve the reproductive health of patients. Family planning agencies often provide family planning services and contraceptives to traditionally underserved, uninsured populations. Many of the women served by these programs might not otherwise be able to obtain needed services. These providers have brought to the Department’s attention a concern that underserved patients are encountering some obstacles to obtaining refills of contraceptives that could be ameliorated by enabling agencies to increase their capacity to supply refills. Currently, the law permits only authorized prescribers, nurses and pharmacists to dispense these medications to patients. Many of the family planning sites, however, cannot afford to provide a practitioner on site, everyday, to provide a refill of these medications. It is also difficult to obtain such persons in geographically isolated areas or areas where it is difficult to recruit health care providers. Because there may not be a practitioner on site, women who come to the provider for family planning services may not be able to obtain a supply of contraceptives at that time. Their options are to come back another time or to seek the contraceptives from a pharmacy, which would require further time, effort and expense. These obstacles to access increase the chances that the patient will fail to obtain contraceptives in a timely fashion, with a correspondingly increased risk of an unplanned pregnancy.”

Dr. Carrow continued, “Department staff have concluded that access to these medication refills needs to be expanded and that this expansion can be accomplished by allowing additional staff to provide refills with the appropriate protections to ensure patient health and safety. The provision of refills by staff should also have additional benefits, including increasing the number of patients receiving contraceptive services, decreasing waiting times for access to services, providing more culturally competent services and enabling clinical staff to spend more time providing clinical

services to patients.”

Staff explained that the family planning agencies would be required to provide medical oversight by a licensed practitioner. Moreover, the regulations would require additional safeguards, including written protocols and procedures, approved curricula and training, limited formulary, labeling requirements, counseling by the authorized prescriber, reporting of medication errors and adverse events, drug controls and maintenance of records. These requirements would ensure the safety of contraceptive refill dispensing by agency personnel.”

Staff expects to hold a public hearing on this matter in March of 2005. Discussion followed by the Council. Council Member Sherman said, “You are telling me the Department is proposing regulations -- that is putting this in the hands of the physicians, setting up something like this, rather than pharmacists?” Dr. Carrow replied, “Currently physicians and nurses and other prescribers are able to dispense these medications in family planning clinics. That is occurring now, has been occurring for twenty years. The difference that we are applying here is to broaden the number of individuals who can provide the medications to the clients in order to make them more accessible to those clients because what happened was the providers approached us and told us the complications that clients have in getting their medications when they need them. This will enable that with appropriate oversight of licensed practitioners.” Mr. Sherman reiterated, “I understand what you are doing but you are doing it physician directed rather than pharmacists designing the system. I would hope that the Department would consult the pharmacists who spend a great deal of their day correcting mistakes and recording the errors made by these same people who are handing out these prescriptions, these medications. I am not talking about hearsay. I am talking about 18 years behind the bench.” Discussion continued and it was noted that the Department partnered with the Board of Pharmacy and the Board of Nursing in developing these proposed regulations and further that pharmacists that work for the Department participated. Mr. Sherman asked if the Board of Registration of Pharmacy, the Massachusetts Pharmaceutical Association and DEA were consulted. Chair Ferguson stated that, “Mr. Sherman is requesting that staff connect with these entities.” Dr. Carrow responded, “The proposed regulations will go to public hearing and we will also seek input from all those groups and that DEA and the FDA and others will have the opportunity to comment on the regulations.” Discussion continued with Council Member Thayer inquiring about dispensing and Dr. Carrow said, “...[This does not include] all elements that would be involved in dispensing by a pharmacist, but would be indicative of what would be involved in dispensing from a physician’s office, and that does include selection of the physician’s office, selection of the product, although as we said, it is a refill, so that is according to the order of the physician. The product would have to be selected to match the order of the physician. Then there is limited labeling that involves the name, date of dispensing, the name of the client, the date of dispensing, the individual who dispensed the medication. All other information that would be required, such as instructions for use, cautionary statements, possible adverse events, that would have to be provided either in the literature that comes with the medication or by the practitioner, and it is also provided by the practitioner at the initial prescription to the client, as well as in discussions with counselors at various times in which the clients come in to get counseling.” It was noted that the nature of the medication is to be manufacturer pre-packaged and pre-labeled so that it can just be handed over to the client. Mr. Sherman noted, “I have no quarrel with what is going on. It is just the design of the system, alright - left in the hands of the physician who, in my recollection, does not get any education in drug

dispensing in four years of medical school.” Mr. Thayer asked about the definition of ‘dispensing’. It was noted that the definition is not noted in these proposed regulations because it is already codified in existing regulations.

Dr. Carrow noted that the proposed regulations are more rigorous in terms of the labeling/dispensing requirements of existing regulations. He said, “What we are doing here is adding standards to what already exists and adding a little bit of extra personnel to be able to hand-out the medication. In terms of what has to be on the label that is defined in Number 7 of the draft regulation. It must contain all the elements in A&B there. That is, the prescriber’s name, address and telephone number, the date of dispensing, the name of the client. Those elements are not required to be on the label today. That is added. In B, the name, dosage form, strength, quantity of the contraceptives, clear, simple, brief directions for use, and the cautionary statements, possible adverse events, for example, and the date on which the medication will expire. That second set is usually included in the manufacturer labeling. So that would be existent today. The first set in A, all would be required, even if dispensed by a nurse or physician. All those medications in the agencies would require all those elements on the labeling.”

Chair Ferguson added, “I want to be clear that today’s discussion is just a presentation of some proposed regulations which have not gone to public hearing...The questions that are being asked are questions that we can get the answers to the members of the Council before any formal activity occurs.”

Discussion continued. Mr. Thayer asked the meaning of the term ‘authorized agents’. Dr. Carrow stated, “The physician. This is a physician directed program and anyone authorized by the physician would be able to do that, as long as they met the qualifications and requirements of the regulation.” Mr. Sherman had more labeling questions, he said in part, “...Where is the name of the entity, the licensee, Planned Parenthood Leagues of Brookline, Inc., 1306 Commonwealth Avenue, the license number? Did somebody think of everything? Wrong. They didn’t. There is a reason why the name of the institution is on there because, if they find Ms. Jones lying in the snow somewhere, if they have to find out the pharmacy or physician that wrote the prescription, they might or might not find that person...That is why it should be designed by a pharmacist...”

Dr. Sterne, Council Member, inquired, “Is there a provision for the records in terms of a lot number?” Ms. Karen Edlund, Director, Family Planning Program, Department of Public Health responded. She said, “That is currently happening in the clinics. They already have drug logs with lot numbers, and it is also in the medical records, and that is something we look at when we go out and review the programs. That is currently happening. We certainly can make specific reference to that in the regulations.” Mr. Sherman asked what the impediments or problems have been for the clinics. Ms. Edlund responded, “There’s a number of issues, we have seventy-five sites across the state, and we have a lot of rural sites that may be open once a week, once every two weeks, where there is actually a clinician there, and if someone comes in to get their pills and the clinician is not there, they can’t get them...It is my job to oversee all these clinics. There are issues about rural sites and clinical staff not being available. A lot of our other sites also don’t have clinicians there every day. Friday is a big day to pick up your pills, and a lot of the time they don’t have a clinician there. So the client would have to come back on Monday, when the clinician is there. So, their hours of operation are limited. There is always a counselor there, someone who can talk

to the client, give them condoms, or whatever they might need, but in terms of prescriptive medications, they often don't have the staff there."

Discussion continued, Mr. Sherman said in part, "...We have to make these [contraceptive medications] ready and available to these people. However, to jump through the hoop for the provider without the input of some systems engineer, or someone educated in putting together a pharmacy dispensing system is a hell of a lot more important now than pushing this through..." Dr. Carrow, replied, "With all due respect sir, we had pharmacists on this panel. We had Chuck Young, Executive Director of the Board of Pharmacy. We had Tim McIntyre, who is a CMS Certified Pharmacist Surveyor for the Division of Health Care Quality. We had Adele Audet, who is Assistant Director of the Drug Control Program. Three pharmacists sat on every single discussion that we had on these regulations." Mr. Sherman said, "I am not quarreling with their credentials. Did you have anybody there who fills two hundred prescriptions a day, whose pharmacy is down the street from a Planned Parenthood Clinic, somebody in Brookline, somebody in Brighton who knows what the problems are with these things? That is what you need, somebody who has been there, done that...not the physician...Get a pharmacist who does it every day. Just pick up the phone book and find one." Dr. Carrow replied, "We can certainly do that." Mr. Sherman reiterated, "I am saying, if there is going to be a system, it has got to be a system that is designed by somebody who knows how to do the pharmacy dispensing. If you are going to do it, do it right."

Chair Ferguson added, "Right. What we need to do before we get to the next step is be clear and work with the Association to look at the processes that are being put in place, and to balance that against the fact that it is already – we are already moving in that direction. From my perspective, the ease with which people can attain these medications is very important and it has never been more important that it is today. We need to balance all of those things against each other, and you have a few suggestions about how to make the next round of this as smooth as possible."

NO VOTE/INFORMATION ONLY

REQUEST FOR APPROVAL OF AMENDMENTS TO 248 CMR 1.0-10.00: THE STATE PLUMBING CODE AND FUEL GAS CODE REGULATIONS:

Mr. Howard Wensley, Designate of the Commissioner, Department of Public Health, accompanied by Stephanie Zierten, Counsel, Joseph Peluso, Executive Director, Board of Examiners, and Gas Fitters. Mr. Wensley said, "...The reason we are before you today is requesting that Council approve amendments to the regulations of the Mass. Plumbing Board. These regulations were last amended, at least in any meaningful way, back in 1996 and they were long past due. In 1985, the Legislature eliminated the statutory requirement M.G.L.c.142§13, that the Department of Public Health approve the regulations for the plumbing code. However, the Legislature did not delete the separate statutory provision in M.G.L.c.142§21, that requires the Department of Public Health to approve any amendments to the plumbing code regulations governing construction in state buildings. Since the plumbing code combines requirements for state buildings and plumbing into one set of rules, it is still necessary for the Department of Public Health to approve any amendments to the plumbing code."

Mr. Wensley continued, "There were some significant changes made to the regulations, including primarily one of the major ones, which is reorganization and putting the code into language that people could understand. A lot of it was previously in paragraph form rather than in outline form. It was difficult to read. It was broken up primarily into two sections; a gas section and a plumbing section, and some of the administrative sections, even though they were the same, were in the plumbing section and in the gas section, so they were all brought together. There is now a section dealing with the administration of the code such things as licenses and registration, Board recognition of product design and testing. One of the unique things about this board is, it has to approve all plumbing fixtures and piping that is installed here in Massachusetts – so any new toilets coming out, come before the Board. It also deals with the imposition of disciplinary sanctions and the complaint handling process. The code moved forward and incorporated updates of technical standards, primarily dealing with the National Fuel and Gas Code, and the National Fire Protection Association. The references in the code were quite dated previously, and were not dealing with current technology and updates. As far as the plumbing code itself is concerned, the plumbing part of it, again the code is bringing the regulations up to current standards in new technology. We included the expanded use of what is PEX tubing, PVC and ABS, which basically is a plastic type material, which I think is going to revolutionize the practice of plumbing in Massachusetts. Most of these have already been approved by most other states. Also, we will eliminate the cast iron water piping with lead or asbestos joints and asbestos cement pipe. I will not read the six hundred pages of regulations. We are asking for approval."

After consideration, upon motion made and duly seconded, it was voted: (unanimously) [Council Member Sherman not present to vote] to approve the Request for **Approval of Amendments to 248.CRM 1.0-10.00: The State Plumbing Code and Fuel Gas Code Regulations**; that a copy be forwarded to the Secretary of the Commonwealth; and that a copy be attached and made a part of this Record as **Exhibit Number 14,803**.

DETERMINATION OF NEED PROGRAM:

COMPLIANCE MEMORANDUM: PREVIOUSLY APPROVED DON PROJECT NO. 4-3A05 OF NEWTON-WELLESLEY HOSPITAL – REQUEST FOR A SIGNIFICANT CHANGE:

Ms. Joan Gorga, Acting Director, Determination of Need Program, presented Newton-Wellesley Hospital's request for a significant change. Ms. Gorga said, "Newton-Wellesley Hospital is before you this morning seeking modification of a condition of their previously approved project, No. 4-3A05, for acquisition of a mobile Positron Emission Tomography Computerized Axial Tomography or PET/CT scanner. Newton-Wellesley originally offered and was approved in May of 2002 for a one hundred percent equity contribution of the 2.2 million dollar cost of the scanner. The hospital is now requesting revision of the condition and offering a twenty percent equity contribution in order to take advantage of a current low interest lease financing rate. This would free the hospital to invest a portion of the MCE rather than purchasing the unit and the hospital would realize two hundred and seventy-one thousand dollars on that investment after making the lease payments. With one hundred percent equity financing, on the other hand, the hospital would be required to pay the vendor upon receipt of the unit and would forego income available to it through investment. Staff finds that the proposed change is reasonable, and in light of past similar

decisions, will reduce the opportunity cost to the hospital and therefore staff is recommending approval of their request, as described on page 3 of the memorandum.”

After consideration, upon motion made and duly seconded, it was voted (unanimously) [Council Member Sherman not present to vote] to **approve the request by Previously Approved DoN Project No 4-3A05 of Newton-Wellesley Hospital** for a significant change to modify a condition of approval relating to project financing, based on staff’s findings noted below and further that the amendment satisfies the Procedure for Significant Changes found at 105 CMR 100.756 of the DoN Regulations. This amendment is subject to the following conditions:

1. Newton Wellesley’s Hospital shall contribute 20% equity contribution toward the final approved MCE of DoN Project No. 4-3A05.
2. All conditions attached to the original and amended DoN Project No. 4-3A05 shall remain in effect.

Background and Staff Analysis as recorded in Staff’s Memorandum to the Council, dated February 22, 2005:

Background:

May 28, 2002: A notice of DoN for Project No. 4-3A05 was issued to Newton-Wellesley Hospital to acquire a mobile PET scanner to be located at on a pad adjacent to the Nuclear Medicine Section of the Hospital’s Radiology Department. The MCE associated with the project was \$2,014,000 (August 2001 dollars). A condition of project approval required financing of the MCE with 100% equity contribution, as originally proposed in the application.

August 25, 2004: The holder filed a request for a minor change to approved but not yet implemented DoN Project No. 4-3A05 to acquire a mobile PET/CT rather than a PET scanner and to increase the MCE to \$2,200,000 (August 2004 dollars) from \$2,014,000 (August 2001 dollars).

October 20, 2004: The DoN Director approved the minor change request to unimplemented DoN Project No. 4-3A05 to acquire a mobile PET/CT rather than a PET scanner and to increase the MCE to \$2,200,000 (August 2004 dollars) from \$2,014,000 (August 2001 dollars). The development of PET/CT scanners has decreased scan times, and increased diagnostic capability and accuracy.

January 14, 2005: The holder filed a request for a significant change to DoN Project No. 4-3A05 to modify a condition of approval and change the method of financing of the increased MCE, to \$2,425,000 (February 2005 dollars) from 100% equity contribution to 20% equity and an operating lease. In addition the holder requested minor changes to acquire a fixed rather than a mobile PET/CT scanner and to increase the MCE from \$2,200,000 (August 2004 dollars) to \$2,425,000 (February 2005 dollars).

Staff Analysis:

The holder states that the proposed amendment will allow the Hospital to make more prudent use of advancing technology by acquiring and installing a fixed unit in the Radiology Department rather than a mobile unit as originally planned. Construction costs related to the installation of the fixed scanner will increase the approved MCE by \$225,000. The resulting increase in the MCE is 9.5% which is less than 10% of the inflation adjusted, originally approved total expenditure and could not reasonably be foreseen by the holder.

In addition, the Hospital seeks revision of the condition requiring 100% equity financing and has suggested financing options that ensure more efficient and effective overall use of the Hospital's limited resources. Supporting documentation submitted with the request indicates that the capital lease would allow the Hospital to take advantage of a current low interest lease financing rate of 3.85% for the five year lease. The opportunity to fund the equipment through lease financing would free the Hospital to invest a significant portion of the MCE amount. Investing the \$2,425,000 conservatively at the five-year U.S. Treasury rate of 3.57%, the Hospital would realize \$271,529 in earnings after the quarterly lease payments. With 100% equity financing the Hospital would be required to pay the vendor on receipt of the PET/CT unit and would forego considerable income otherwise available to it through such investment.

In reviewing the request for modification of the condition concerning project financing, Staff has examined whether the proposed financing of the MCE was reasonable in light of past decisions, was not foreseeable at the time the application was filed and was beyond the holder's control. Consistent with Council's past decisions, Staff finds that the proposed change in project financing was unforeseen at the time the application was filed, was beyond the control of the holder and will reduce the project's opportunity costs to the holder. Staff has also determined that the request for minor changes, which do not require Council's action, is reasonable and will be approved.

Project Application No. 2-3A79 of UMass Memorial Medical Center for new construction of an addition to the existing facility to replace eight (8) operating rooms as part of a new three-story addition at the University campus:

Mr. Jere Page, Senior Analyst, Determination of Need Program, presented the UMass Memorial Medical Center application to the Council. Mr. Page noted, "...The applicant, UMass Memorial Medical Center is in front of the Council today seeking approval for new construction and renovation on the Medical Center's University campus in Worcester. The project involves new construction to replace eight existing OR's and two new OR's, as well as adding space for pre-/post-operative recovery and a post-anesthesia care unit, as part of a new three-story addition on the University's campus. It is all part of the Lakeside Expansion Project, a 128 million dollar project that is ongoing as we speak."

Mr. Page continued, "There is also renovation involved in this project to expand two existing surgical suites. The project is intended to address the increasing growth of inpatient and outpatient surgical volume on the University campus, where the thirty year old operating rooms are undersized and out of date. This has resulted in reduced efficiency in patient flow and longer turnover time for many surgical patients. Because of its complex patient caseload, the University

campus needs to be able to provide advanced levels of surgical care in an environment that is supported by 21st century medical technology. The Medical Center is confident that the construction and replacement with new operating rooms, and renovation of the two existing surgical suites will significantly improve the overall operating efficiencies and allow the residents of Central Massachusetts greater access to high level surgical procedures and state of the art technology. It is expected that this particular project will be completed by January 2006. The recommended maximum capital expenditure is \$22,698,494 dollars in July 2004 dollars, which will be financed with a 40% equity contribution of 9 million dollars in available funds, as well as fund raising efforts, which have been successful.

He said further, "You may have read recently that UMass received 12.5 million dollars to contribute to the overall Lakeside Expansion Project. The remaining 60% of the MCE is 13 million. Six million will be funded by tax exempt bonds as issued by the Massachusetts Health and Educational Facilities Authority. Funding for community initiatives associated with this project is significant. A total of just over 1.1 million dollars will be provided over five years, and this funding will provide for various community programs in the Medical Center's service area. These programs will be established through a request for proposal process in coordination with the local Worcester Community Health Network area. In conclusion, the staff is recommending approval of this project with the conditions on pages 10-12 of the staff summary."

Discussion followed and Council Member Thayer, Jr., inquired about the funding of the project – was this private money or taxpayers funding the project. Ms. Rosemary Rotty, Manager of Financial Planning for UMass Medical Center responded, "Some of the funding will come from our Fiscal Year 2003 operations which had a net gain of eight million dollars. This year, we have 14.8 million dollars in operations. Other funding is going to be coming from a plant drive, which Jere mentioned and the bond financing. We will go to market probably in May or June and seek a bond financing." Discussion continued and it was noted that operations is hospital money gained from charging fees to people and the equity contribution will come from that source. It does not include money from third party payers.

Ms. Janet Slemenda, Council Member asked why the DoN guidelines are 19 years old. Mr. Page answered, "1986 is when the guidelines were promulgated. We receive only about one of these kinds of project per year so it has not been feasible for staff to review them. When the guidelines were originally done, it was the work of two or three different architects and a lot of health professionals. We sort of use that as a guideline but as you read in the staff summary, it is not truly helpful in most cases. In this particular case, with the OR's, we have roughly 4,000 square feet per OR suite and those old guidelines recommend 2500 so they don't account for improvements in high tech equipment." Chair Ferguson added, "I think that was one of the issues that we kind of talked a little bit about at our retreat, in terms of what kind of updating we need to do on a variety of regulations and that is certainly something that can be pursued. One of the reasons I like to do things in a non-regulatory way as often as possible is that, when you put it into regulations, to change it opens up a whole can of worms that is often very difficult to get through." Ms. Slemenda added, "so, it is easier just to accept the guideline." Dr. Sterne moved to accept staff recommendation.

After consideration, upon motion made and duly seconded, it was voted (unanimously) [Council Member Sherman not present to vote] to approve **Project Application No. 2-3A79 of UMass Memorial Medical Center, Inc.**, based on staff findings, with a revised maximum capital expenditure of \$22,698,494 (July 2004 dollars) and first year incremental operating costs of \$11,538,000 (July 2004 dollars). A staff summary is attached and made a part of this record as **Exhibit No. 14,804**. This approval provides for new construction to replace eight existing operating rooms (OR's) and add two new OR's, as well as add space for pre/post-operative recovery and a post anesthesia care unit (PACU) as part of a new three-story addition on the Medical Center's University campus. Renovation is also proposed to expand two existing surgical suites. This Determination is subject to the following conditions:

1. The applicant shall accept the maximum capital expenditure of \$22,698,494 (July 2004 dollars) as the final cost figure except for those increases allowed pursuant to 105 CMR 100.751 and 752.
2. The total gross square feet (GSF) for this project shall be a total of 43,537 GSF for new construction to replace eight existing OR's, add two new OR's, and add space for pre/post-operative recovery and a PACU; and 3,500 GSF for renovation to expand two existing surgical suites.
3. The Applicant shall provide the following missing elements of a professional medical interpreter service:
 - A revised Plan of Care document to provide an accurate list of available language services
 - A plan to reach out to the agencies and natural support groups of new LEP communities to ensure their members have first-hand information about UMMMC programs and the availability of interpreter services
 - Development of a protocol to ensure that emerging languages are added and sustained to meet the needs of all LEP patients
 - A plan to ensure interpreter coverage of all campuses and programs under the auspices of UMMMC

A plan to address these interpreter service elements shall be submitted to the Office of Multicultural Health (OMH) within 120 days of the DoN approval. In addition, The Applicant shall notify OMH of any substantial changes to its Interpreter Services Program, and progress reports shall be submitted annually to OMH on the anniversary date of the DoN approval. Also, the Applicant shall follow recommended National Standards for Culturally and Linguistically Appropriate Services (CLAS) in Health care.

4. The applicant, in coordination with Common Pathways [Community Health Network Area (CHNA #8)] has agreed, as a condition of approval, to the following principles and process

for the distribution of funds (\$1,134,925 July 2004 dollars) for community health service initiatives to be established through a subsequent Request for Proposal (RFP) process.

- This process shall be a subset of the larger Common Pathways process and the larger UMass Memorial Community Benefits Advisory Committee process.
- The process for distribution of all of UMass Memorial DoN monies (“DoN monies”) shall be made pursuant to a variation of the UMass Memorial Community Benefits Advisory Committee (“CBAC”) process, as outlined below:
 - A DoN Subcommittee of the CBAC shall be established for the purpose of making determinations on all projects to be funded from the DoN monies.
 - The Subcommittee shall be comprised of five individuals from the CBAC, five individuals from the Common Pathways (CHNA #8) as well as the UMass Memorial Vice President for Community Benefits, as a non-voting member, who will convene and support the work of Subcommittee.
 - The Subcommittee shall solicit proposals from the community, pursuant to a transparent and objective Request for Proposal process, and make determinations on the selection of projects. All RFP solicitations shall indicate that priority shall be given to projects falling within the community priorities and that all projects must meet the Factor 9 criteria, as further outlined below. All RFP solicitations and awards shall indicate they are being made pursuant to a joint UMass Memorial/Common Pathways process.
 - In making determinations on projects for funding, the DoN Subcommittee shall be guided by the following regulatory language of Factor 9 of the DoN Regulations governing community health service initiatives, including any appropriate written guidance to be issued by DPH to the extent it is applied uniformly to all DoN’s in the state.
 - All projects shall be “for the provision of primary and preventive health care services for underserved populations in the project’s service area (or other area approved by the Department) and reasonably related to the project.”
 - In making determinations on projects for funding the DoN Subcommittee shall give priority to those projects that meet the community priorities to be established through the Common Pathways

community engagement process by Common Pathways.

- It shall be incumbent on the DoN Subcommittee to reach agreement on all projects to be recommended.
 - All projects funded through this process be acknowledged to have been funded by UMass Memorial Health Care. The total amount of funds for this Community Health Services Initiative shall be \$1,134,925 (5% of project cost of \$22,698,494).
 - Within 30 days of approval of the DON, \$15,000 in funds (to be deducted from the total of \$1,134,925) shall be allocated to Common Pathways for the purpose of supporting its infrastructure development and community engagement including community convening. The remaining \$1,119,925 or \$223,985 per year will be distributed by the DON Subcommittee over the 5-year period.
- On an annual basis, the DoN Common Pathways shall be entitled to use \$12,500 (total of \$62,500 over five years) of the \$223,985 annual allotment to support the development and ongoing functioning of Common Pathways.

This approval was based on the following Staff Findings:

1. The Applicant is proposing new construction to replace eight existing operating rooms (OR's) and add two new OR's, as well as add space for pre/post-operative recovery, and a PACU as part of a new three-story addition on the Medical Center's University campus. Renovation is also proposed to expand two existing surgical suites.
2. The health planning process for the project was satisfactory.
3. The proposed new construction and renovation is supported by current and projected acute care utilization, as discussed under the Health Care Requirements factor of the Staff Summary.
4. The project, with adherence to a certain condition, meets the operational objectives factor of the DoN Regulations.
5. The project, with adherence to a certain condition, meets the standards compliance factor of the DoN Regulations.
6. The recommended maximum capital expenditure of \$22,698,494 (July 2004 dollars) is reasonable compared to similar, previously approved projects.
7. The recommended operating costs of \$11,538,000 (July 2004 dollars) are reasonable compared to similar, previously approved projects.

8. The project is financially feasible and within the financial capability of the applicant.
9. The project meets the relative merit requirements of the DoN Regulations.
10. The proposed community health service initiatives, with adherence to a certain condition, are consistent with the DoN Regulations.

The meeting adjourned at 11:10 a.m.

Christine C. Ferguson
Chair

LMH/lmh